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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,595	09/29/2004	Kaoru Asano	Q83447	3089

23373 7590 04/20/2006  
SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

WHALEY, PABLO S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/509,595	ASANO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, 14-17, and 19 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/29/04 ; 5/16/05</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### *APPLICANTS' ELECTION*

Applicants' election without traverse of Group I drawn to Claims 1-10, 12, and 14-20, and election of Species A (iii) drawn to a position within a gene region containing both a glaucoma-related gene coding region and a glaucoma-related upstream region, and Species B drawn to the substitution at position 4037 of SEQ ID No. 1, filed 1/27/2006, is acknowledged. The specie election drawn to Specie A (iii) is hereby withdrawn for the expedience of prosecution. Claims 7, 8, 11, and 13 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/27/2006.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are Claims 1-6, 9, 10, 12, and 14-20.

### *INFORMATION DISCLOSURE STATEMENT*

The information disclosure statements filed Sept. 29, 2004 and May 16, 2005 have been considered in full.

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### **OBJECTIONS**

Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because claim 12 appears to depend from two different claims, one of which is non-elected. Accordingly, the claim 12 has not been further treated on the merits.

### **CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 9, 14-17, and 19 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 1-6, 9, 14-17, and 19 are directed to a process that does not recite either a physical transformation of matter nor a practical application. For example, instant claim 1 recites steps of "detecting a variation in nucleic acid bases" and "predicting any future development of glaucoma." However, these steps do not result in a physical transformation of matter. It is noted that processes may be statutory where they recite a concrete, tangible, and useful result (i.e. a practical application). However, no actual, concrete result is recited in the claims, nor is any useful result "produced" in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory. See the Guidelines for Patent Eligible Subject Matter (USPTO, 1300 OG 142, Nov. 22, 2005).

### CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 9 and 10 are rejected under 35 U.S.C. 102 (e) as being anticipated by Sarfarazi et al. (Pub. No: US2004/0191798; Priority: Dec. 24, 2001).

Sarfarazi et al. teach methods of detection, prognosis and diagnosis of the presence or absence of optineurin-associated glaucoma or of an optineurin-associated increased risk of glaucoma [Abstract], as in instant claim 1. More specifically, Sarfarazi et al. teach the following aspects of the instant invention:

- Detection of sequence alterations (i.e. variants, deletion, or substitutions) in the optineurin gene associated with glaucoma [0023], [0178], as in instant claims 1 and 4.
- Alterations include insertions or deletions of one or more single nucleotides resulting a mutation of the gene [0023], as in instant claim 1.
- Measuring alterations (i.e. variations) in optineurin genes as an indicator of optineurin-associated glaucoma [0053],[0054], which correlates to using "variation as an index" as in instant claim 1.
- Primary open angle glaucoma [claim 28], as in instant claim 9.

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- Kits useful for detection comprising hybridization probes and oligonucleotides and means for amplification of nucleic acids comprising optineurin gene [0056], as in instant claim 10.

Claims 1, 2, 4, 9, and 10 are rejected under 35 U.S.C. 102 (e) as being anticipated by Stone et al. (US 6,956,103; Priority: Apr. 28,1994).

Stone et al. teach methods for detecting mutations in genes that correlate with the existence or predisposition to the development of glaucoma [Col. 2, lines 11-16], as in instant claim 1. More specifically, Stone et al. teach the following aspects of the instant invention:

- A method of determining if a subject is at risk for glaucoma resulting from a mutant GLC1A gene [Col. 3, lines 59-62], which correlates to "predicting any future...using said variation as an index" as in instant claim 1.
- Detecting presence or absence of genetic alterations of genes encoding myocilin polypeptide (i.e. MYOC gene) or the mis-expression of the GLC1A gene [Col. 52, lines 1-10], which is a teaching for the MYOC gene and primary open angle glaucoma, as in instant claims 1, 2, 4, and 9.
- Detection techniques include the use of up to 250,000 oligonucleotide probes bound to a solid support for detecting SNPs, each capable of hybridizing to part of a GLC1A gene [Col. 52, lines 54-60], [Col. 53, lines 1-10], which correlates to "at least two" positions as in instant claim 1, and oligonucleotides as in instant claim 10.

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**CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**